

REMARKS

This Response is submitted in reply to the final Office Action mailed on August 22, 2007. No fee is due in connection with this Response. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-203 on the account statement.

Claims 9-26 are pending in this application. Claims 1-8 and 27-34 were previously withdrawn. In the Office Action, Claims 9-26 are rejected under 35 U.S.C. §103. For the reasons set forth below, Applicants respectfully submit that the rejection should be withdrawn.

In the Office Action, Claims 9-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of U.S. Patent No. 4,317,838 to Cherukuri et al. ("*Cherukuri*") and WO 99/44436 to Stahl ("*Stahl*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claims 9 and 18 recite, in part, a product comprising a gum center and a coating comprising at least 50% by weight of the product. In alternative embodiments, the present claims provide improved products for delivering a medicament or agent to an individual. To this end, chewing gum, specifically a coated chewing gum product, is provided including a medicament or agent. The medicament or agent is present within the coating. The coating substantially encloses a gum center (the water soluble portion and insoluble base portion) and comprises at least 50% by weight of the product. In other words, the coating comprising the medicament must have a weight equal to or greater than that of the gum center. In contrast, Applicants respectfully submit that, even if combinable, the cited references fail to disclose or suggest every element of the present claims.

It has been surprisingly found that chewing a coated chewing gum with a medicament or agent in the coating, or in certain situations even placing the coated chewing gum in the mouth, releases the medicament or agent from the chewing gum. Continuing to chew the chewing gum creates a pressure within the buccal cavity forcing the agent or medicament directly into the systemic system of the individual through the oral mucosa contained in the buccal cavity. This greatly enhances the absorption of the medicament or agent into the systemic system of the individual as well as the bioavailability of the medicament or agent within the system.

By having a coating comprising at least 50% by weight of the entire chewing gum product, a larger amount of medicament or agent can be placed in the coating. As a result, chewing the gum releases more medicament or agent into the saliva in higher concentrations. During continual chewing, the medicament or agent in the saliva is then forced through the oral mucosa in the buccal cavity due to the pressure created by the chewing. A higher concentration of medicament or agent in the saliva results in a higher concentration gradient in the oral cavity. This improves absorption of the medicament or agent through the oral mucosa.

It has also been surprisingly found that an increase in the absorption of the medicament or agent through the oral mucosa is achieved when compared to typical oral administration. In other words, the medicament or agent is absorbed into the system of an individual more quickly through the oral mucosa than if it was swallowed as in a typical oral administration. Indeed, the absorption of the medicament or agent through the oral mucosa approaches that of a parental administration (e.g. intravenous or intramuscular injection), and bioavailability is also much greater than oral administration.

Cherukuri fails to disclose or suggest every element of the present claims. For example, *Cherukuri* fails to disclose or suggest a coating comprising at least 50% by weight of the product as required, in part, by Claims 9 and 18. Though the Patent Office alleges that *Cherukuri* does indeed disclose this limitation (see, Office Action, page 2), none of the weight percentages disclosed teach a coating comprising at least 50% by weight of the overall product. Instead, the ranges are with respect to the weight of the coating syrup, dusting mix or the gum base. See, for example, *Cherukuri*, column 2, lines 40-55 (“by weight of the coating syrup”); column 3, line 50 – column 4, line 4 (“by weight of the dusting mix”); column 4, lines 50-55 (“by weight of the gum center”); column 4, lines 55-58 (“by weight of the coating”), and column 5, lines 43-47 (“by weight of the gum base”).

The Patent Office asserts that *Cherukuri*’s teaching that the application of coating syrup and dusting mix are continued until the average gum piece weight reaches about 90% of the required coating weight (see, *Cherukuri*, column 4, lines 25-29) meets the claimed limitation of “the coating comprising at least 50% by weight of the chewing gum product” of the present claims. Applicants respectfully disagree. Instead, *Cherukuri* is describing an example of how many coating and dusting applications should be used to achieve a percentage of the required coating weight before only coating applications are used. For example, when actually referring

to weight % coating in the total product, *Cherukuri* only discloses at most a level of 35% by weight coating in the coated chewing gum tablet. See, *Cherukuri*, column 4, lines 29-34 and column 7, lines 15-19. Applying 10 to 12 coats of coating syrup and 7 to 9 coats of dusting achieves 90% of the required 35% by weight coating. Three additional coating layers are applied without using any dusting layers to achieve the remaining 10% of the 35% by weight coating.

Stahl also fails to disclose or suggest a coating comprising at least 50% by weight of the product as required, in part, by Claims 9 and 18. Instead, the Patent Office relies upon *Stahl* for arguably teaching a medicament in the coating along with a sweetener, an element the Office Action admits *Cherukuri* lacks. See, Office Action, page 3.

In sum, *Cherukuri* and *Stahl* fail to disclose or suggest every element of the present claims and fail to even recognize the advantages, benefits and/or properties of a consumable product having coating comprising at least 50% by weight of the product in accordance with the present claims. For at least the reasons discussed above, the combination of *Cherukuri* and *Stahl* fails to teach, suggest, or even disclose all of the elements of Claims 9 and 18 and Claims 10-17 and 19-26 that depend from Claims 9 and 18, and thus, fail to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 9-26 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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Dated: October 9, 2007